DEC 2 3 2013

510k Summary
AVAIRA (enfilcon A) Sphere and Toric Contact Lenses
12/20/2013

Applicant: CooperVision, Inc.
6150 Stoneridge Mall Road, Suite 370
Pleasanton, CA 94588 USA

Applicant Contact: Annette Nelson
Senior Regulatory Affairs Specialist
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Date Prepared: November 15, 2013

Device Trade Name: AVAIRA Sphere and Toric Soft Contact Lenses

Common/Usual Name: Enfilcon A Soft (Hydrophilic) Contact Lens

Classification Name: Soft (Hydrophilic) Contact Lens, Daily Wear, Disposable

Device Classification: Class II (21 CFR 886.5925); Product Codes MVN and LPL

Predicate Devices: AVAIRA Sphere and Toric Soft Contact Lenses (K071736/K113759)

Device Description:

The Avaira (enfilcon A) soft contact lens is a daily wear silicone hydrogel contact lens that is not surface treated and is characterized by a high oxygen permeability (Dk). The lens material, *enfilcon A*, is composed of silicone macromers cross linked with other monomers, incorporating phthalocyanine blue as an integrated handling tint. A UV blocker is added to reduce the amount of ultraviolet light transmitted into the eye. The Avaira *(enfilcon A)* Soft (hydrophilic) contact lenses are a hemispherical shell. This 510(k) submission covers a process modification to add a step to the preparation of the monomer mixture. The physical properties and dimensions of the finished lenses are unchanged from predicate 510(k)s.

Intended Use:

SPHERICAL:
Avaira (*enfilcon A*) SPHERE Soft Contact lenses are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes. The

lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity.

TORIC:
Avaira (*enfilcon A*) TORIC Soft Contact lenses are indicated for the correction of ametropia (myopia or hyperopia with astigmatism) in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters and astigmatic corrections from -0.25 to -10.00 diopters.

Physiochemical Studies
In-vitro studies measuring the physical, optical and chemical properties of lenses subjected to the modified manufacturing process were performed. The results show there is no significant change to the physicochemical properties of the lenses.

Tested Characteristics	Results
Refractive Index, Total Extractables, Monomer Residuals, Ionoflux, Contact Angle, UV Transmission, Modulus, Elongation, Tensile Strength, and Power Conformance	Pass

Clinical Studies
In-vivo clinical studies were not required for this change, as the dimensions, formulation, lens manufacturing process, and product specifications remain the same.

Conclusion

Validity of Scientific Data

Physiochemical studies were conducted by CooperVision following scientific protocols.

Substantial Equivalence

The information presented in this submission establishes the substantial equivalence of the modified AVAIRA (enfilcon A) SPHERE and TORIC daily wear contact lenses to the predicate devices. The following table summarizes the substantial equivalence comparison information.

Substantial Equivalence Comparison		
Characteristic	**AVAIRA SPHERE and TORIC (K071736/K113759)**	**AVAIRA SPHERE and TORIC (This Submission)**
Indications for Use AVAIRA SPHERE	Correction of ametropia in aphakic and non-aphakic persons with non-diseased eyes and astigmatism ≤2.00 diopters	Same
Indications for Use AVAIRA TORIC	Correction of ametropia (myopia or hyperopia with astigmatism) in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters and astigmatic correction from -0.25 to -10.00 diopters	Same
Single Use	Single-use, disposable	Same
Replacement	Daily Wear, disinfect using chemical or hydrogen peroxide disinfectant when prescribed for planned replacement	Same
Material USAN Name	enfilcon A	Same
Principle of Operation	Designed to fit over corneal surface of eye to provide corrective refraction for functional conditions of the eye	Same
Refractive Index	1.40	Same
Oxygen Permeability x 10^{-11}	100 (cm^2/sec)(ml O_2)/ml*mmHg)	Same
Base Curve	8.2 to 9.2 mm	Same
Diameter	13.5 to 15.0 mm	Same
Power Range	-20.00 to +20.00 D	Same
Cylinder Power	-0.25 to -10.00 D	Same
Water Content (avg, %wt)	46%	46%
Monomer sonication step	No	Yes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 23, 2013

CooperVision, Inc.
% Ms. Annette Nelson
Senior Regulatory Affairs Specialist
6150 Stoneridge Mall Road, Suite 370
Pleasanton, CA 94588

Re: K133627
Trade/Device Name: AVAIRA Sphere and Toric Soft Contact Lenses
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL
Secondary Product Code: MVN
Dated: November 15, 2013
Received: November 26, 2013

Dear Ms. Nelson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: Registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Deborah L. Falls -S

for Malvina B. Eydelman. M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Indications for Use

510(k) Number: K133627

Device Name: AVAIRA (enfilcon A) Sphere and Toric Soft Contact Lenses

Indications For Use:

AVAIRA (enfilcon A) SPHERE Soft (Hydrophilic) Contact Lenses are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity.

AVAIRA (enfilcon A) TORIC Soft (Hydrophilic) Contact Lenses are indicated for the correction of visual ametropia (myopia or hyperopia with astigmatism) in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters and astigmatic corrections from -0.25 to -10.00 diopters.

DAILY DISPOSABLE:
The AVAIRA (enfilcon A) Soft (hydrophilic) Contact Lenses are indicated for single-use disposable wear.

FREQUENT REPLACEMENT:
The AVAIRA (enfilcon A) Soft (hydrophilic) Contact Lenses are indicated for daily wear. When prescribed for planned replacement the lens may be disinfected using a chemical or hydrogen peroxide disinfecting system.

Prescription Use___X___ AND/OR Over-The-Counter Use_____
(part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jeffrey M. Brocious -S
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(Division Sign-Off)
Division of Ophthalmic and Ear, Nose, and Throat Devices
510(k) Number: K133627